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PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Group Art Unit: 1633
Attorney
Docket: 21419-91513
Applicant: Bosworth & Vögeli

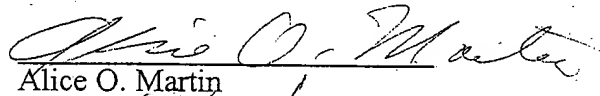
Invention: *COMPOSITIONS TO IDENTIFY SWINE
GENETICALLY RESISTANT TO F18 E. COLI
ASSOCIATED DISEASES*

Serial No: 09/844,268
Filed: April 27, 2001
Examiner: N/A

Certificate Under 37 CFR 1.8(a)

I hereby certify that this correspondence is
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Assistant Commissioner for Patents,
Washington, D.C. 20231

on November 8, 2001


Alice O. Martin

Dated: 11/8/01

INFORMATION DISCLOSURE STATEMENT

JUN 30 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

TECH CENTER 1600/2900

Sir:

This statement is filed in the application identified above pursuant to 37 C.F.R. §
1.56. No representation is intended that a complete search has been made of relevant
publications or that no more relevant publications than listed below are available. A copy of
each publication is not provided pursuant to 37 C.F.R. 1.98(d) as they were previously
submitted to the Office on February 22, 2001 for U.S. Ser. No. 09/443,766 and relied upon
for this application. The filing of this Statement shall not be construed to be an admission
that the information cited in the Statement is, or is considered to be, material to patentability
as defined in § 1.56(b).

PUBLICATIONSU.S. PATENTS

| <u>Patent No.</u> | <u>Issue Date</u> | <u>Inventor</u> |
|-------------------|-------------------|--------------------------|
| 5,358,649 | October 25, 1994 | MacLennan, <i>et al.</i> |
| 5,552,144 | September 3, 1996 | Samuel, <i>et al.</i> |
| 5,625,124 | April 29, 1997 | Falk, <i>et al.</i> |

FOREIGN PATENTS

| <u>Publication No.</u> | <u>Publication Date</u> | <u>Country</u> |
|------------------------|-------------------------|----------------|
| WO 86/04604 | August 14, 1986 | PCT (DENMARK) |
| WO 94/13811 | June 23, 1994 | PCT (EUROPE) |
| WO 96/28967 | September 26, 1996 | PCT (JAPAN) |

Abstract: The hyperacute rejection occurring in the transplantation of tissues of a non-primatal mammal into a higher primate can be mitigated by transferring foreign genes of a higher primate, which express a sugar transferase, into a non-primatal mammal so as to express sugar-chain antigens of the higher primate.

OTHER REFERENCES

BOSWORTH, B.T., *et al.* (1996) "Vaccination With Genetically Modified Shiga-Like Toxin Iie Prevents Edema Disease in Swine." *Infect and Immun* 64(1): 55-60.

COHNEY, S., *et al.* (1996) "Molecular Cloning of the Gene Coding for Pig $\alpha 1 \rightarrow 2$ fucosyltransferase." *Immunogenet* 40: 76-79.

DEVEREUX, J., *et al.* (1984) "A Comprehensive Set of Sequence Analysis Programs for the VAX." *Nucl Acids Res* 12(1): 387-395.

FUJIL, J., *et al.* (1991) "Identification of a Mutation in Porcine Ryanodine Receptor Associated with Malignant Hyperthermia." *Science* 253: 448-451.

GAFFNEY, R.A., *et al.* (1994) "Effect of Lewis Blood Group Antigen Expression on Bacterial Adherence to COS-1 Cells." *Infect and Immun* 62(7): 3022-3026.

INFORMATION DISCLOSURE STATEMENT (October 27, 1998)

KELLY, R.J., *et al.* (1994) "Molecular Basis for H Blood Group Deficiency in Bombay (O_h) and Para-Bombay Individuals." *Proc Natl Acad Sci* 91: 5843-5847.

MEIJERINK, E., *et al.* (1997) "Two $\alpha(1,2)$ fucosyltransferase Genes on Porcine Chromosome 6q11 are Closely Linked to the Blood Group Inhibitor (*S*) and *Escherichia coli* F18 Receptor (ECF18R) Loci." *Mammal Genome* 8: 736-741.

NAGY, B., *et al.* (1992) "Susceptibility of Porcine Intestine to Pilus-Mediated Adhesion by Some Isolates of Piliated Enterotoxigenic *Escherichia coli* Increases with Age." *Infect and Immun* 60(4): 1285-1294.

VÖGELI, P., *et al.* (1996) "Genes Specifying Receptors for F18 Fimbriated *Escherichia coli*, Causing Oedema Disease and Postweaning Diarrhoea in Pigs, Map to Chromosome 6." *Schweiz Arch Tierheilk* 139(11): 479-484.

VÖGELI, P., *et al.* (1997) "Ein Molekular Test für den Nachweis des *E.-coli*-F18-Rezeptors: ein Durchbruch im Kampf gegen Ödemkrankheit und Absetzdurchfall beim Schwein." *Schweiz Arch Tierheilk* 139(11): 479-484.


Abstract: Oedema disease and post-weaning diarrhoea in swine are associated with the colonization of the intestine with toxigenic *Escherichia (E.) Coli* bacteria of various serotypes. Colonization depends on specific binding between adhesive fimbriae and receptors on the enterocytes. The demonstration of these receptors allows the identification of susceptible and resistant pigs. Direct sequencing of the $\alpha(1,2)$ fucosyltransferase gene (FUT1) in swine being either susceptible or resistant to adhesion by F18 fimbriated *E. coli* revealed a mutation at basepair 307 (M307). Analysis of the mutation in Swiss Landrace and Large White families showed close linkage with the locus controlling resistance and susceptibility to *E. coli* F18 adhesion (ECF 18R). The FUT1(M307) mutation is a good marker for selection of *E. coli* of F18 adhesion resistant animals. The mutation is found with variable frequencies in Duroc, Hampshire and Pietrain pigs as well.

None of the above-cited publications are believed to disclose or suggest the invention recited in the claims of the above-identified application or the priority date of the application is before the publication date. It is therefore believed that the claimed invention is patentably distinguishable over these publications.

Please charge any fees that might be due in connection with this Information Disclosure
Statement to our Deposit Account No. 10-0435.

Respectfully submitted,

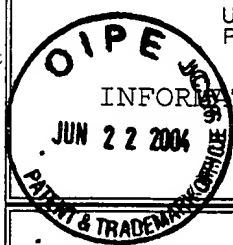
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U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO. 21419-91513

SERIAL No.
09/844,268

APPLICANTS Bosworth & Vögeli

FILING DATE April 27, 2001

GROUP

U.S. PATENT DOCUMENTS

| *Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date if Appropriate |
|-------------------|----|-----------------|---------------|--------------------------|-------|----------|----------------------------|
| | AA | 5,358,649 | Oct. 25, 1994 | MacLennan, <i>et al.</i> | 435 | 6 | Dec. 20, 1991 |
| | AB | 5,552,144 | Sep. 3, 1996 | Samuel, <i>et al.</i> | 424 | 236.1 | Jan. 10, 1994 |
| | AC | 5,625,124 | Apr. 29, 1997 | Falk, <i>et al.</i> | 800 | 2 | Jul. 11, 1994 |
| | AD | | | | | | |
| | AE | | | | | | |
| | AF | | | | | | JUN 30 2004 |
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| | AI | | | | | | |
| | AJ | | | | | | |
| | AK | | | | | | |

FOREIGN PATENT DOCUMENTS

| | | Document Number | Date | Country | Class | Subclass | Translation Yes No |
|--|----|-----------------|---------------|--------------|-------|----------|--------------------|
| | AL | WO 86/04604 | Aug. 14, 1986 | PCT(DENMARK) | | | X |
| | AM | WO 94/13811 | Jun. 23, 1994 | PCT(EUROPE) | | | X |
| | AN | WO 96/28967 | Sep. 26, 1996 | PCT(JAPAN) | | | X |
| | AO | | | | | | |
| | AP | | | | | | |

OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)

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| | AR | BOSWORTH, B.T., <i>et al.</i> (1996) "Vaccination With Genetically Modified Shiga-Like Toxin Ie Prevents Edema Disease I n Swine." <i>Infect and Immun</i> 64(1): 55-60. |
| | AS | COHNEY, S., <i>et al.</i> (1996) "Molecular Cloning of the Gene Coding for Pig $\alpha 1 \rightarrow 2$ fucosyltransferase." <i>Immunogenet</i> 40: 76-79. |
| | AT | DEVEREUX, J., <i>et al.</i> (1984) "A Comprehensive Set of Sequence Analysis Programs for the VAX." <i>Nucl Acids Res</i> 12(1): 387-395. |
| | AU | FUJIL, J., <i>et al.</i> (1991) "Identification of a Mutation in Porcine Ryanodine Receptor Associated with Malignant Hyperthermia." <i>Science</i> 253: 448-451. |
| | AV | GAFFNEY, R.A., <i>et al.</i> (1994) "Effect of Lewis Blood Group Antigen Expression on Bacterial Adherence to COS-1 Cells." <i>Infect and Immun</i> 62(7): 3022-3026. |
| | AW | INFORMATION DISCLOSURE STATEMENT (October 27, 1998). |
| | AX | KELLY, R.J., <i>et al.</i> (1994) "Molecular Basis for H Blood Group Deficiency in Bombay (O _h) and Para-Bombay Individuals." <i>Proc Natl Acad Sci</i> 91: 5843-5847. |
| | AY | MEIJERINK, E., <i>et al.</i> (1997) "Two $\alpha(1,2)$ fucosyltransferase Genes on Porcine Chromosome 6q11 are Closely Linked to the Blood Group Inhibitor (S) and <i>Escherichia coli</i> F18 Receptor (ECF18R) Loci." <i>Mammal Genome</i> 8: 736-741. |
| | AZ | NAGY, B., <i>et al.</i> (1992) "Susceptibility of Porcine Intestine to Pilus-Mediated Adhesion by Some Isolates of Piliated Enterotoxigenic <i>Escherichia coli</i> Increases with Age." <i>Infect and Immun</i> 60(4): 1285-1294. |
| | BA | VÖGELI, P., <i>et al.</i> (1996) "Genes Specifying Receptors for F18 Fimbriated <i>Escherichia coli</i> , Causing Oedema Disease and Postweaning Diarrhoea in Pigs, Map to Chromosome 6." <i>Schweiz Arch Tierheilk</i> 139(11): 479-484. |
| | BB | VÖGELI, P., <i>et al.</i> (1997) "Ein Molekular Test für den Nachweis des <i>E.-coli</i> -F18-Rezeptors: ein Durchbruch im Kampf gegen Oedemkrankheit und Absetzdurchfall beim Schwein." <i>Schweiz Arch Tierheilk</i> 139(11): 479-484. |

Examiner

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609.

Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.



June 30 2004

TECH. CENTER 1600/2900

Applicant: Brad Bosworth and Peter Vogeli
Filed Date: April 27, 2001
Serial No.: 09/844,268
Attorney Docket No.: 21419/91513
Title: COMPOSITIONS TO IDENTIFY SWINE
GENETICALLY RESISTANT TO F18 *E. COLI*
ASSOCIATED DISEASES

The following was sent to United States Patent and
Trademark Office:

• Information Disclosure Statement

Mailed via Regular Mail on November 8, 2001.

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Reg. No. 35,601

